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TechnegasPlus

Technegas Generator

USER MANUAL

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Manufactured in Australia by:
Cyclomedica Australia Pty Ltd

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NOTICES

Attention

The information found in this manual is the latest information at the time of delivery. However, Cyclomedica reserves the right to change specifications and recommended procedures without prior notice.

Should this occur and affect the use of your TechnegasPlus Generator, you will be advised of any upgrades or recommended procedural changes which will be accompanied by amendment sheets for this manual.

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PICTORIAL REFERENCE

Power On Lamp
Argon Gas Inlet
Mains Switch

Argon Gas Inlet - Push back to connect Hose.

Argon Gas Inlet with Hose connected

TECHNEGASPLUS TECHNEGAS GENERATOR

What is Technegas?
Technegas is an ultra-fine suspension of carbon nano-particles labelled with technetium (Tc-99m).
Technegas preparation takes place in a specially designed machine, called the TechnegasPlus Generator.

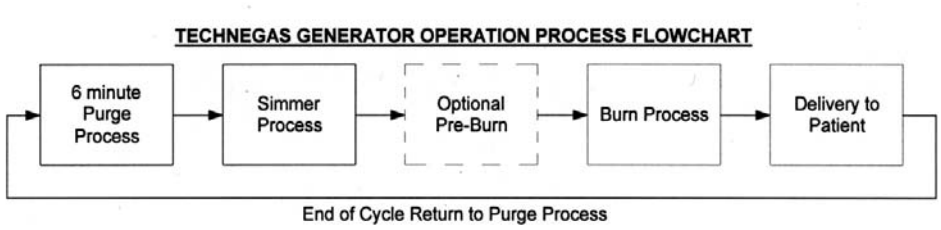
The Technegas particles have been determined to be hexagonal platelets of metallic technetium (Tc-99m) closely encapsulated with a thin layer of graphitic carbon, the size distribution of Technegas particles being around 30-60 nm with 80% of the particles being below 100 nm. The ratio of the platelet thickness to diameter is around 1:10 in most cases.

Prolonged storage of Technegas promotes aggregation into larger particles and the migration of those particles to the walls of the chamber, therefore Technegas is intended to be administered to the patient within 10 minutes of its generation. To prevent accidental use of expired diagnostic agent, after 10 minutes, the TechnegasPlus Generator inhibits the delivery to the patient and the chamber is automatically purged through a filter system to trap any excess Technegas.

How does the TechnegasPlus Generator Work??
The Cyclomedica TechnegasPlus Generator is an electro-mechanical device weighing approximately 100 kilograms, mounted on a trolley. The TechnegasPlus Generator is fully self contained in terms of its own operation and radiation shielding and the various steps of Technegas production are under the automated control of a microprocessor with front panel display prompts and simple push button operation.

The TechnegasPlus Generator is essentially a miniature high temperature furnace operated from mains voltage. It uses a combination of graphite and an Argon atmosphere to reduce and then vaporise Technetium Generator eluant (sodium pertechnetate) in a chamber.

It does this by first drying the eluant to remove the water from the saline carrier solution, then raising the graphite Pulmotec Crucible™ to an ideal temperature of 2750 °C for a period between 3 and 15 seconds to produce the Technegas particles. A pre-burn step of 1650°C may also be introduced in the process prior to the final burn.



An inbuilt optical sensor detects the light given off by the hot Pulmotec Crucible™ enabling the Pulmotec Crucible™ temperature to be kept within specified limits during the heating cycles. The burn process releases in excess of 60% of the Technetium into the vapour phase. A manually operated exit port, the Patient Valve in the chamber enables the patient to inhale the suspended Technegas, which by depositing on the surfaces of the alveoli of the lung enables the
functioning airways distribution to be mapped by the standard nuclear medicine technology, namely a gamma camera.

USER RESPONSIBILITY

- **Incorrect equipment operation may occur if the operational environment is unsuitable.** The User of the TechnegasPlus Generator is responsible for providing an appropriate operational environment as defined by the specifications contained in this manual. The TechnegasPlus Generator will meet the specifications described in this manual and in the package inserts and labels affixed to its consumables when it is installed and operated in accordance with those labels and instructions.

- **Keep the equipment in good order.** User Maintenance should be carried out by the user at the recommended periods defined in the manual to ensure reliable operation. The User should also ensure that the manufacturer recommended 6 monthly services are strictly observed and carried out by your local distributor.

- **A defective product should not be used**. Any faults must be promptly reported. Parts that are worn, defective or suspected of any defect should be replaced immediately. Cyclomedica recommends in the above instance that the User contact their local distributor for service advice.

- The TechnegasPlus Generator bears regulatory marks to show compliance to Medical Device standards and regulations. No part of this product should be repaired or modified in any way other than in accordance with those standards and the specifications defined by Cyclomedica..

- The user of the TechnegasPlus Generator and its accessories shall take sole responsibility for any malfunction which results from the improper use, or faulty maintenance, improper repair, damage, alteration or modification by anyone other than an authorised Cyclomedica representative.

- For correct operation, the User must ensure that TechnegasPlus Generator is allowed adequate time to charge its internal battery by following the instructions given in this manual. While batteries may naturally fail over time, they will last longer and give you better service if kept properly charged.

Precautions & Warnings

- **USE ONLY Solution of Sodium Pertechnetate (Tc99m) of European Pharmacopoeia grade or equivalent in the TechnegasPlus Generator**

- Before adding Tc99m eluate, always wet the Pulmotec Crucible™ using ethanol adding the Pertechnetate immediately after. Wetting the Pulmotec Crucible™ ensures air cannot be trapped under the Pertechnetate and cause bubbling over of the Pulmotec Crucible™ sides during the simmer process. Do not use methylated alcohol as it may leave residues on evaporation that could lead to pyrolysis products in the gas genera tion stage. Also, care must be taken when handling Pulmotec Crucibles™ to avoid the introduction of foreign substances from any source. Always use clean gloves and inspect the Pulmotec Crucible™ at the time of installation into the TechnegasPlus Generator.

- Ensure that the Pulmotec Crucible™ is not overfilled. The meniscus should be CONCAVE or FLAT not convex.

- Always turn off the Argon gas when the supply is disconnected from the TechnegasPlus Generator to avoid waste. For safety, use the order of operations recommended by the Regulator supplier or manufacturer.

- Dispose of the used consumables as contaminated waste, both will be radioactive and biologically hazardous after use.

- In the interests of reliable operation and basic hygiene, do not attempt to use a Patient Administration Set (PAS) on more than one patient.

- Do not clean a PAS and attempt to use it again. Both gas and liquid sterilising damage the valve mechanism and the filter material, causing unreliable operation, reduced radiation filtering ability and potential bacterial contamination of the machine. **Disposal of the PAS is mandatory after a single use.**

- **Do not allow repairs to be carried out on the TechnegasPlus Generator by unauthorised personnel.**

- Do not insert cleaning brushes or other foreign objects through the various valves, openings or holes in the device or its consumables. Damage may result which will make the unit unserviceable.

- Do not use the unit for any other purpose than that specifically indicated in the product literature.

- Do not autoclave the unit or its consumables as this will damage the circuitry and other components.

Safe Handling of Compressed Gas Cylinders

Cylinders of compressed gas are very heavy, and unstable and should be kept restrained at all times. Follow your site's Occupation Health and Safety requirements for handling Compressed Gas Cylinders. Cyclomedica Australia Pty Ltd can in no way be held liable for negligence in the restraining or handling of high pressure gas cylinders. The responsibility of Cyclomedica Australia Pty Ltd, is limited to the Technegas machine up to the low pressure regulator, and where supplied by Cyclomedica, the high pressure regulator.
Cyclomedica Australia Pty Ltd recommends that the Argon gas supply be piped in from an external location as is the usual practice with hospital reticulated gases. Given the lifetime of the technology, the investment in this safety precaution is minor.

Use of Gloves

During the various steps of generation and use of Technegas, the following considerations are paramount in maintaining a clean working environment and in minimising the risk of contamination:
Whenever the internal parts of the generator are handled or open during loading of new Pulmotec Crucibles™ and radioactivity, or during contact replacement or any other procedure, gloves must be worn.
Gloves must be removed and disposed of using standard radiation handling techniques immediately prior to touching anything else such as the drawer close interlock knob and the CLOSE button.

Traceability

Please register ownership with your local distributor at the time of installation by completing the Warranty Card. Should there be any change of ownership of the Generator then your local distributor should be notified in writing immediately. From time to time service notes, changes in literature, device notifications etc., may become necessary. Cyclomedica maintains traceability of its products as a requirement of the Regulatory Authorities.

Safe Patient Delivery of Technegas

To avoid the escape of Technegas into the room the following steps should be observed;

- Never open the patient delivery valve until the generator is coupled to the patient using the PAS or a Cyclomedica approved alternative mouthpiece.

- Always ensure that the patient continues to breathe through the PAS whilst connected to the Technegas unit with the delivery knob released for at least FIVE breaths after the cessation of Technegas inhalation. This maneouvre clears Technegas from the delivery tubing and the patient's conducting airways.

- If you suspect that the patient will not comply with the mouthpiece of the administration set choose a more suitable delivery system from the range of alternatives available (such as a face-mask). Note that this may be done in the course of the inhalation procedure.

Moving the TechnegasPlus Generator Safely

- When moving the TechnegasPlus Generator, disengage the wheel locks and always push or pull the unit by using the hand grip panels provided moving the TechnegasPlus Generator at a rate of no more than a slow walking pace. Do not attempt to move the TechnegasPlus Generator with the wheel locks engaged or in a manner that you cannot safely control.
  eg: swinging the generator around or moving it at a speed faster than a slow walking pace.

- Do not wheel the TechnegasPlus Generator Trolley over obstacles on the floor or over uneven surfaces that may block or seize the wheels eg: gaps between an elevator and the floor, gamma camera rails and cables.

- Do not load the trolley with heavy items such as Gas Bottles for transport. Always move Gas Bottles and other heavy equipment using specialised transport equipment that is appropriate for carrying such items.

Installation Requirements

Power Supply

The User must provide a mains power line dedicated for use with the TechnegasPlus Generator - 200 to 230/240V, 50/60Hz rated at 20 Amperes.

Argon Gas Supply

The User must provide High Purity or Laboratory Grade Argon ≥99.99% pure.

Warning!

Some Argon gas mixtures are sold for use in arc welding (Argoshield). They usually contain small quantities of oxygen and other gases.
These mixtures must not be used with the TechnegasPlus Generator as they are not appropriate for human use.

Additional items required

- a 1mL Syringe capable of dispensing 0.1 ml.
- Syringe shield.
- Disposable gloves.
- Pure ethanol, greater than 95%.
- Watch glass or Petrie Dish.
- 1 ml needle-less syringe.
- Forceps (supplied with Technegas Generator.)

General Requirements

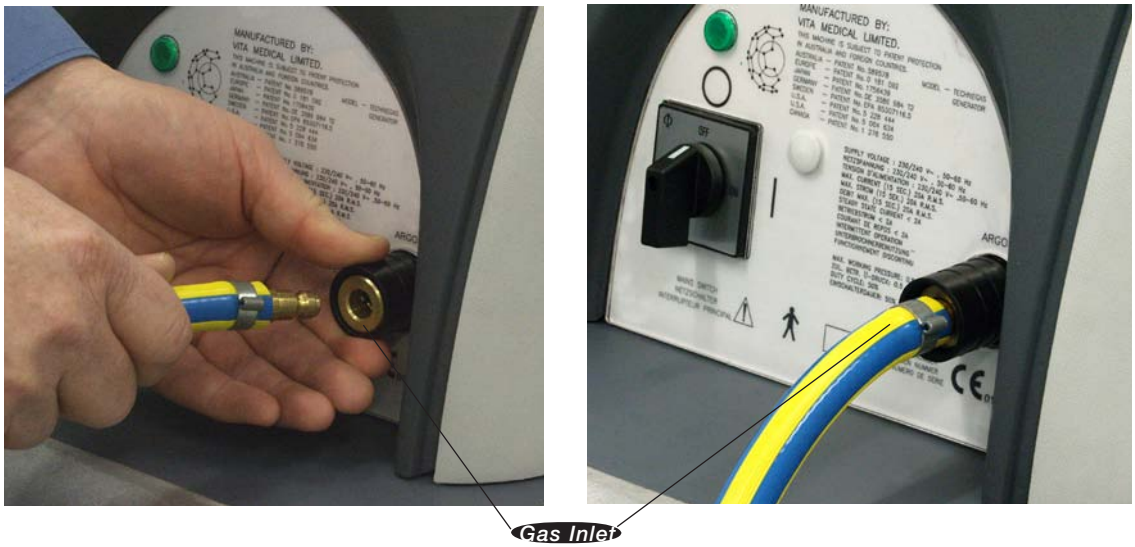
- Assign an area within the Nuclear Medicine department, preferably near the imaging room, for production of Technegas and storage of the unit.
- Allow space for the safe storage of used Pulmotec Crucibles™ and PAS for a minimum of five days before final disposal as non-radioactive waste or as per the regulations and/or licenses of your local Competent Authorities.

Battery Charging

Plug the Technegas unit into the 20 ampere electrical power outlet and switch on using the main switch located at the rear of the generator. A flat battery will not be evident until you try to deliver Technegas to your patient! You are advised to leave the unit plugged in and turned on when not in use to keep the battery fully charged.

Operating the 'CANCEL' Button.

The CANCEL button needs to be pressed TWICE within two seconds to activate a "CANCEL" operation. This eliminates the risk of canceling an operation accidentally.



Connecting the Argon Gas

Before commencing the production cycle, the Argon gas should be connected and turned on. To do this, plug in the gas outlet hose to the gas inlet of the Technegas Generator, and ensure the self-latching mechanism has engaged. Where a high pressure gas bottle is used, ensure that the bottle is securely fixed to a wall or as per your local Occupational Health and Safety requirements.

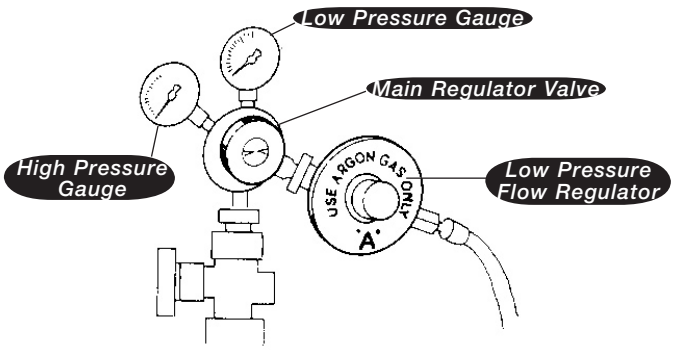
Operating the Gas Bottle Regulator

Ensure that the regulator mechanism is firmly bolted to the gas supply. Ensure that the regulator is fully off then turn on the gas at the bottle. Rotate the main regulator valve until the low pressure gauge registers 14 litres per minute or as indicated by the "green" area of some regulators.

The following order of operations for turning on and off the Argon gas regulator is recommended to avoid damage to the regulator itself. Note that turning the main regulator valve clockwise turns the gas **ON** and counter-clockwise turns it **OFF**.

TO TURN ON: Bottle On first, then Regulator On.

TO TURN OFF: Regulator Off first, then Bottle Off.



- Switch on the Technegas Generator, initially the display will show the name Cyclomedica Australia Pty Ltd for 4 seconds. If a purge has not been carried out since the last Technegas generation, then it will then check if the drawer is closed and purge for 6 minutes.
This purge is to ensure that no radioactive Technegas from a previous test will escape into the atmosphere when the drawer is opened

Please Note: At the completion of the patient delivery process and the removal of the PAS from the Generator, Cyclomedica recommends that the operator reconnects the Generator to the mains power, switches it on and allows the 6 minute purge cycle to be carried out. This will keep the machine cleaner and allow a period of battery recharging.

The display will then read:

OPEN DRAWER TO
CHANGE CRUCIBLE

• To do this, simply press OPEN. There is no need to hold down the button, however, if necessary pressing the CANCEL button will immediately stop the drawer moving. If there was a Pulmotec Crucible™ in the machine from a previous burn, it will have been broken, so it, or its pieces, should be removed first (this is to ensure that the Pulmotec Crucible™ is not accidentally re-used).

There is a small stainless steel tray immediately below the Pulmotec Crucible™ which is removable to facilitate this step. The contacts which hold the Pulmotec Crucible™ can be opened by using the lever under the platform on the left-hand side.

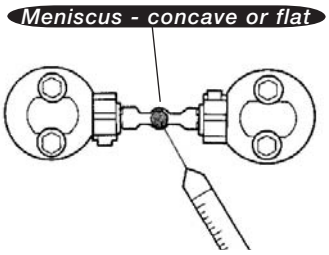
CAUTION The lever and all other internal components of the generator are contaminated during Technegas generation. Be sure disposable gloves are worn at this stage and take care to practice proper anti-contamination procedures by removing and replacing gloves between touching contaminated and non-contaminated components.

Preparing and Fitting the Pulmotec Crucible™
For the Preparation of Technegas, Users should follow the details in the Package Insert for the Pulmotec Crucible™ (Instructions for Use and handling) making reference to the Package Insert for the Patient Administration Set (PAS) and this Manual as required.

• Remove the Pulmotec Crucible™ from its packaging using the forceps supplied with the Generator, and place it on a watch glass for suitable support.
• Wet the well of the Pulmotec Crucible™ by filling with absolute or 95% ethyl alcohol using a 1 ml needle-less syringe. Draw back any excess ethanol with the same syringe leaving the Pulmotec Crucible™ wet with ethanol.
• Pick up the wetted Pulmotec Crucible™ using the forceps holding them in the right hand with the forceps gripping the top and the bottom of the Pulmotec Crucible™, not the sides. Top and bottom are determined by having the well of the Pulmotec Crucible™ in the upright position. The Pulmotec Crucible™ axis should be at an approx. 40° to the right hand side of the forceps.
• With a gloved left hand push the lever under the platform towards the back of the machine, thus opening the contacts. Place one end of the Pulmotec Crucible™ into the left hand contact and align the other end of the Pulmotec Crucible™ with the right hand contact. Slowly release the lever so that the right hand contact is made. Unless good contact is made a low Technegas yield may result. Rotate the Pulmotec Crucible™ gently backwards and forwards on its axis a few times prior to simmering to ensure good contact. Rotate the Pulmotec Crucible™ to ensure the well cavity is upright.

• CAUTION This procedure should be carried out carefully, as the crucible is very brittle.

• Load the crucible with Tc-99m generator eluant (note the crucible must still be wet from the ethanol before the Tc-99m is added – if not, repeat the wetting process), use a 1ml syringe with a suitable needle and ensure that no bubble of liquid rises above the top of the crucible (maximum volume 110ul for standard crucibles)



Technetium Generator Eluate - Recommended Pulmotec Crucible™ loading is between 400 and 900 MBq (10-25mCi) of Sodium Pertechnetate in 0.14ml (normal saline). Thus a radioactive concentration of 4000 to 9000 MBq/ml (100 to 250mCi/ml) is required. If such a high radioactive concentration eluate is not available it is possible to carry out multiple crucible loadings by interrupting the automatic generation cycle after the evaporation phase (Simmer), this is done by pressing the CANCEL button **TWICE** in two seconds, opening the drawer, re-filling and re-evaporating. Please note that the crucible does not require re-wetting with ethanol prior to re-filling.

• To close the drawer, press the Drawer Interlock Knob on the top FIRST, then the CLOSE button. Keep both depressed until the drawer is fully closed and the drawer light has gone out.

If either is released before the drawer has stopped moving it will immediately re-open. This two handed operation is a safety precaution.

Do not attempt to put anything in the drawer opening, nor to interfere with the process as you may damage the seal of the generator. Do not operate the mechanism if you suspect anything may obstruct normal operation.

CAUTION - WHENEVER THE GENERATOR IS NOT IN USE, THE DRAWER MUST BE CLOSED TO AVOID ACCIDENTAL CONTAMINATION OF PERSONNEL.

The display will then read:

PRESS START TO
INITIATE SIMMER

• When START is pressed the chamber will be checked for correct sealing by a leak test, then the simmering, purging starts. This cycle is 6 minutes in length, indicated by a count-down time that is displayed during this stage. Only the CANCEL button is active during this time.

Gas Flow Monitor
Gas flow into the unit is continuously monitored . If the gas flow is too high or low because of an emptying bottle or a valve not fully on, the process will halt and the unit will 'beep' while displaying the message to 'Gas Flow Too High/Low'. As soon as the fault is corrected, the machine will resume the process.

Case Temperature Too High
The Technegas Generator has a recommended Duty Cycle of 2 Gas Generations **only** per hour. Where used more frequently, the Generator Chamber may become too hot for effective use. In this case a message is displayed to indicate to the user that they must wait for the Generator to cool before continuing. We have introduced a limit of 49 degrees Celsius to the case temperature, above which the unit will not operate and the message 'Case Temperature Too High - Wait' will be displayed

The unit is now ready for the final stage of Technegas generation. Before proceeding further, position the patient ready for inhalation and open a fresh PAS beside them as reassurance. The patient must be familiar and comfortable with breathing through the mouthpiece while their nose is blocked with the clamp supplied. If the patient defeats the mouthpiece on exhalation then a percentage of the inhaled Technegas can be released into the room. This can cause a rise in camera background radiation.

The 6 minute simmer and purge routine creates a convenient time to rehearse the patient in the procedure and minimise the risk of failure.

If the generator is left longer than 15 minutes while preparing the patient then the generator will recheck the presence of argon gas. This is repeated every 15 minutes thereafter. Note that the burn stage cannot be commenced until after the check is completed and the prompt appears to START the burn.

• Press the START button now and the burn will commence, raising crucible temperature above 2700°C for 15 seconds.

When the burn is complete the display will read

VERIFYING BURN

- this message holds for 3 seconds and then changes to:

DISCONNECT THE
MAINS PLEASE

Your Technegas is now prepared and ready for inhalation by the patient. Refer to the Section of this Manual on Administration of Technegas.

• Disconnect the Argon gas (be sure to turn the Argon supply off at the regulator as recommended before disconnecting the Argon, otherwise wastage will occur) then wheel the machine to the camera room. **The Technegas is available to be administered for 10 minutes after generation.** This is indicated by a count-down time on the display. While the mains power has been disconnected the unit remains powered by an internal battery.

• To save battery power and to prevent inadvertent release of Technegas, the machine will disengage the Patient Release Valve. It may be re-engaged any time during the 10 minute Technegas availability period by following the displayed prompt and pressing the START key.

ADMINISTRATION OF TECHNEGAS

Introduction
For best results, Technegas must be administered to the patient as soon as possible after being generated, and certainly within the 10 minutes allowed. The patient should be prepared for administration during the Technegas generation process. Ideally, the patient should be positioned so that the activity entering the lungs can be monitored with a gamma camera as it is delivered.

Recommended Dose
It is recommended that the User consult the Package Insert for the Crucible for details of Dosimetry.

The dose to the patient must be set by the User's Nuclear Medicine Department, please consult your Department Director and/or Radiation Safety Officer.

Administration to the Patient
For the administration of Technegas to a patient, Users should follow the details in the Package Insert for the Patient Administration Set (PAS) making reference to the Package Insert for the Crucible and this Manual as required.

• Select the desired mouthpiece and allow the patient to familiarise themselves with it during the preparation time of Technegas as described in the PAS Package Insert. When ready, fit a nose clip to the patient to prevent the patient breathing through the nose.

Patient posture affects the distribution profile of Technegas in the lungs in response to the gravitational effect on blood distribution. Every effort should be made to ventilate the patient in the same posture as they will adopt for the MAA injection. Experience has shown that wherever possible, patients should be supine and the gamma camera positioned for a posterior view. Body movement and breathing irregularities are greatly reduced if your patient is in a comfortable, but restrained supine position.

• When the patient is prepared, press the START button to produce Technegas.

• When prompted by the Technegas Generator Display, disconnect the unit from the Argon gas and the mains power and wheel the machine to the patient. **Note that it is important to deliver the Technegas as soon as possible after it is generated.**
• Connect the open end of the tubing of the PAS to the generator by pushing it over the Technegas release port and locking the bayonet fitting with a small clockwise twist. Encourage the patient to breathe normally through the mouthpiece. Assure the patient at this time that they are breathing room air.
• Press the START button to release the patient delivery valve.

• When the patient is comfortable and confident breathing through the mouthpiece, request the patient to exhale then press down the patient delivery knob firmly as the patient begins to inhale.

• Ask the patient to breathe in the Technegas described in the Mode of Administration section of the **Crucible Package Insert** using the breathing method best suited to the patient.

IMPORTANT: The administration techniques are described in the Package Insert for the Crucible. The chosen technique will depend on the health condition of the patient.
Method 1: Deep and slow breathing from the residual functional capacity (calm and expiration) followed by a 5 second pause of inspiration.
Method 2: Deep breathing with deep inspirations without pause
Method 3: Rapid and deep inspirations from the residual functional capacity followed by a pause of about 5 seconds in inspiration.

TIP: Encouraging the patient to imitate sucking drink through a straw seems to improve the efficiency of the inhalation.

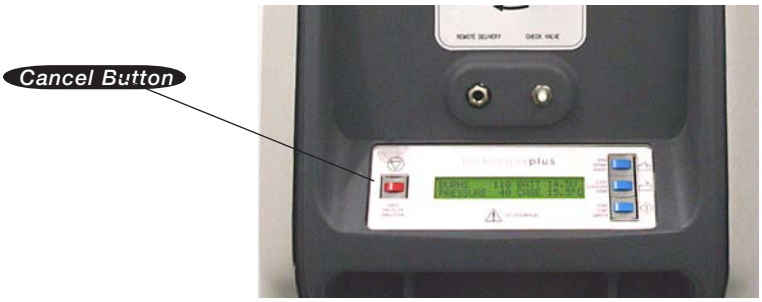
• Watch the count rate and repeat this operation until the required activity is present in the lungs.

• Release the delivery valve after the required activity is present, and allow the patient to breathe air again through the mouthpiece tube assembly. It is important for the patient to breathe through the PAS assembly for five to six breathing cycles after Technegas has been administered before removing it from the Technegas Generator to clear Technegas from the tubing and the patient airways.

NOTE 1: The delivery knob may be pressed and released continually during the inhalation process to regulate intake of Technegas. It bypasses to room air when not depressed.

NOTE 2: Some patients may endeavor to breathe in and out around the mouthpiece, thus defeating the effectiveness of the test and rapidly contaminating the room air. The risk of this can be reduced by carefully explaining the importance of the test to the patient, allowing the patient a practice run with the mouthpiece. (page 20) and if necessary manually holding the lips closed with gloved hands. A disposable mask may also be used. For elderly patients a pleasant tasting gel is available to form a good seal around deeply fissured lips.

• After the patient has received the required amount of Technegas the patient valve should be released and the CANCEL button pressed TWICE in two seconds. The unit will then shut down.



• Return the unit to the preparation area, reconnect the Argon and electrical power, switch on and allow the system to purge any residual Technegas immediately. This will reduce the level of Carbon build up in the chamber in between service calls.

NOTE: It is important to leave electrical power on to the unit to maintain battery charging.

TIP: If the radioactive counts from your patient are too low, the most probable cause is that the patient has defeated the mouthpiece and breathed room air.

PRECAUTIONS

• Cyclomedica recommends that two operators carry out the delivery of Technegas to a patient using the Easy Breather Attachment.

The Easy Breather has been specially developed to assist with the delivery of Technegas to patients who are unable to co-operate with the normal passive delivery system and if available in your market, has been fitted to the TechnegasPlus Technegas Generator. Cyclomedica recommends that two persons, one of whom MUST be qualified and experienced with positive pressure breathing systems, are needed to deliver these radioactive gas-like tracers with minimum risk of creating leakage into the camera room and causing significant airborne contamination.
Note: The requirements for qualifications of personnel experienced in the use of positive pressure breathing systems may differ between institutions or the health systems of various countries. You must ensure that the personnel using the Technegas Easy Breather have relevant experience or experience as necessary under your institution regulations or health system requirements.

• DO NOT use the Easy Breather device as a Resuscitation device.

• Follow your departmental guidelines for controlling cross-contamination. To prevent biological contamination of the Easy Breather, the Technegas Generator and the patient it is important that the resuscitator bag supplied with the Easy Breather be reserved for use only with the Easy Breather and not used for any other purpose.

• Warning: For use of the Easy Breather with Paediatric patients,:
Replace the 1.6 litre Adult Resuscitator Bag with a lower volume paediatric or infant Resuscitator Bag. That a paediatric physician, trained in resuscitation techniques be present during Technegas delivery using an Easy Breather.

• DO NOT squeeze the Resuscitator Bag until delivering Technegas to a Patient and then only after the Patient Valve is depressed. Inadvertent use of the Resuscitator Bag may pressurise the Technegas Generator chamber when the Patient Valve is closed or release Technegas into the atmosphere if the Patient Valve is opened and not delivering Technegas to a patient.

Installing the Resuscitator Bag
• Connect the Resuscitator Bag Non-re-breathing Valve Assembly to the East Breather Manifold connection located on the rear sloping face of the Mk2 Technegas Generator by pressing it firmly into position.

Installing the PAS Filter Check Valve and Pneumatic Control Line
• Using the Pneumatic Control Line (Silicon Hose), connect the PAS Filter Check Valve to the Easy Breather via the hose connection located on the TechnegasPlus Generator Front Display Panel, so that the hose is firmly in position.

Easy Breather Accessory Operating Procedure: Preparation
• Before each use, check the installation of the Technegas Easy Breather Resuscitator Bag following the procedure previously described in this manual.
• Produce Technegas in the normal way, according to the Technegas Plus Generator 'User Manual' instructions
• Transport the Technegas Generator to the Camera room and fit a new PAS to the Technegas Generator.

• The PAS Check Valve and the PAS are mated using a standard tapered coupling. Attach the PAS Check Valve to the end of the PAS filter unit by pushing it firmly over the filter outlet, rotating the PAS Check Valve slightly as you push to engage it to the filter.

Caution: Ensure there are no kinks in the pneumatic control line to the valve.

• Where required, fit the oxygen bag accessory to the Resuscitator Bag, adjust the hospital oxygen supply regulator to deliver about 10 l/min. oxygen from the standard hospital oxygen outlet and plastic tube, and couple the end of the tube to the oxygen inlet nozzle on the Resuscitator Bag.
If the patient is breathing spontaneously, one person stands beside the patient's bed and operates the face mask and the Patient Delivery Valve. The second person squeezes the bag in synchronisation with the patient's breathing.
Note that the face mask must be applied firmly to the patient's face, and the Technegas Patient Delivery Valve pressed as the patient begins to inhale the first breath. This ensures the initial pressurisation of the chamber is utilised to deliver Technegas with maximum efficiency, and minimum risk of leakage.
• **DO NOT** squeeze the Resuscitator Bag until delivering Technegas to a Patient and then only after the Patient Valve is depressed. Inadvertent use of the Resuscitator Bag may pressurise the Technegas Generator chamber when the Patient Valve is closed or release Technegas into the atmosphere if the Patient Valve is opened and not delivering Technegas to a patient.
• **DO NOT** remove the mask once the procedure has started unless the Patient Delivery Valve has been closed or the activity will rapidly flow out into the room and cause contamination problems.

Using the Easy Breather with Spontaneously Breathing Patients
• **DO NOT** squeeze the Resuscitator Bag until delivering Technegas to a Patient and then only after the Patient Valve is depressed. Inadvertent use of the Resuscitator Bag may pressurise the Technegas Generator chamber when the Patient Valve is closed or release Technegas into the atmosphere if the Patient Valve is opened and not delivering Technegas to a patient.
• Open the Patient Delivery Valve on the Technegas Generator, and the person beside the Easy Breather Accessory then controls the breathing cycle of the patient by squeezing the bag to inflate the patient's lungs as the patient inhales. Note that in normal operation the Resuscitator Bag should be squeezed with ONE HAND to deliver Technegas.
• Ensure that there is an inspiratory pause of 3-5 seconds at full inhalation to maximise the deposition of Technegas in the patient's lungs.
• Release hand pressure on the bag and the PAS Check Valve will open to allow the patient to exhale normally through the PAS filter.
• Repeat the process until the pre-determined count-rate on the gamma camera has been reached.
• Once the count-rate on the camera has reached the pre-determined figure, usually after one or two breaths, release the Patient Delivery Valve on the Technegas Generator and remove hand pressure from the bag. Allow the patient to take a further few breaths to clear the tubing and airways of residual Technegas.
• Immediately the procedure is finished, place the delivery tubing and mask (PAS) into a plastic bag and seal it to prevent diffusion of the residual gas into the camera room.
• Remove the oxygen line from the Easy Breather Accessory if it was used.

Using the Easy Breather with Ventilated Patients

• **Important –** only Qualified Medical personnel should operate the Technegas Easy Breather when used on Ventilated Patients.

• **DO NOT** squeeze the Resuscitator Bag until delivering Technegas to a Patient and then only after the Patient Valve is depressed. Inadvertent use of the Resuscitator Bag may pressurise the Technegas Generator chamber when the Patient Valve is closed or release Technegas into the atmosphere if the Patient Valve is opened and not delivering Technegas to a patient.

• If the patient is on a ventilator, ensure the coupling from the PAS to the ventilator connection is the correct size **before commencing the process.** At the end of an exhalation, open the circuit and couple the delivery tube to the ventilator system, as close to the patient's mouth as possible.

• Immediately open the Patient Delivery Valve on the Technegas Generator, and the person beside the Easy Breather Accessory then controls the breathing cycle of the patient by squeezing the bag to inflate the patient's lungs.

• Ensure that there is an inspiratory pause of 3-5 seconds at full inhalation to maximise the deposition of Technegas/Pertechnegas in the patient's lungs.

• Release hand pressure on the bag and the PAS Check Valve will open to allow the patient to exhale normally through the PAS filter.

• Repeat the process until the pre-determined count-rate on the gamma camera has been reached.

• Once the count-rate on the camera has reached the pre-determined figure, usually after one or two breaths, release the patient delivery valve and immediately re-couple the ventilator system to the patient.

• Plug the patient connecting point of the PAS and place it into a plastic bag sealing it to prevent diffusion of activity into the camera room.

• Remove the oxygen line from the Easy Breather Accessory if it was used.

OPERATING THE INTERNAL CRUCIBLE OVEN ACCESSORY *(WHERE FITTED)*

If available if your market area, the Mk2 Technegas Generator has been fitted with a 'Crucible Oven' located inside the Drawer The Crucible Oven has been designed to overcome delays caused by carrying out multiple simmers when they have low activity from their generator. The crucible oven allows the simultaneous preparation of up to 5 crucibles in an Argon atmosphere. It is especially useful when the specific activity of Technetium is low e.g. at the end of the week. Benefits are maximised when the technologist keeps a number of crucibles simmering during the day by progressively refilling for immediate use with the Technegas Generator.

The Crucible Oven operates independently from the Technegas Generator and begins its own simmer cycle each time the Drawer is closed. At the same time, the Technegas Generator may continue to be used to prepare Technegas by following the normal process.

PRECAUTIONS

• The Crucible Oven should ONLY be operated by trained Radiation Workers to avoid risks involving radiation spills, unnecessary radiation exposure or contamination.

OPERATION BY TRAINED RADIATION WORKERS ONLY - OBSERVE RADIATION HAZARD PRECAUTIONS AT ALL TIMES

• The Crucible Oven contains components heated to a high temperature. Use precaution when handling. eg: DO NOT place crucibles in the Crucible Oven by hand, always use forceps when handling crucibles.

• USE ONLY Solution of Sodium Pertechnetate (Tc99m) of European Pharmacopoeia grade or equivalent in the Technegas Generator

OPERATION

Caution: Hot surface present. Do not touch the hot surface as it may result in a burn injury.

To pre-load a crucible with activity using the Crucible Oven, open the Technegas Generator Drawer and fit the wetted crucible(s) into position on the Crucible Oven Heating Plate using forceps. Load the crucible(s) with technetium eluate and close the Drawer.

Fill crucibles **ONLY** with **Sodium Pertechnetate (Tc99m). DO NOT OVERFILL.** A flat or concave meniscus is recommended

Simmering by the Crucible Oven will begin. Up to 5 crucibles may be placed on the Crucible Oven Heating Plate.

Note that the Drawer may only be opened to refill the crucible(s) being prepared during the Technegas cycle when prompted by the display (OPEN DRAWER TO CHANGE CRUCIBLE) or by pressing the CANCEL key **TWICE** during the normal Technegas simmer cycle. Refill the Crucibles and Close the Drawer to start a new Crucible Oven simmer. Any crucibles that are unused after pre-loading on one day may be continued to be pre-loaded on subsequent days until burnt.

If it is necessary to 'double dose' a crucible already fitted between the Contacts, after loading, then press the CANCEL button **TWICE** within two seconds at the end of the simmer cycle. This will allow the drawer to be opened again. There is no need to re-wet the crucible with alcohol.

List of Contaminated Items
- The crucible
- The USED Patient Administration Set (PAS)
- Crucible contacts
- Gloves

NOTE: The crucible and the Patient Administration Set are single use items and should be handled as follows:

Always use disposable gloves during handling contaminated items

The crucible is broken automatically following Technegas generation to prevent accidental re-use which would result in erratic yields. The debris is collected in a tray beneath the contacts, and will contain a residue of radioactivity. It should be treated as low level radioactive waste.

The PAS and mouthpieces should be treated similarly with additional consideration given to the interests of basic hygiene.

The crucible contacts should be changed as specified on pages 30 & 31 and decay stored or disposed of as low level radioactive waste.

Any component removed or replaced from the internal systems must be handled as if it too were contaminated; although, the degree of contamination will depend on the length of time that the unit has stood since last used.

Disposal of Radioactively Contaminated Items
The disposal of radioactive and infectious waste are subject to the regulations and/or the appropriate licenses of the local Competent Authority or Regulatory Body.

Where advice on disposal is required, Cyclomedica Australia Pty Ltd recommends that users contact these administrations.

MESSAGES AND DESCRIPTIONS

'WAIT PURGING CHAMBER'	Indicates that the generator is purging (cleaning) the chamber prior to allowing the drawer to be opened
'OPEN DRAWER TO CHANGE CRUCIBLE'	Indicates that the drawer is ready to be opened to load a crucible
'LOAD CRUCIBLE THEN CLOSE DRAWER'	Indicates that the operator should install a moistened crucible, load the crucible with Technetium-99m and close the drawer
'CHANGE CONTACTS OR CLOSE DRAWER'	The drawer can now be closed until it is a convenient time to change the contacts. If the contacts are to be changed, switch the power off with the drawer open and refer to the 'User Maintenance and Service Page XX"
'PRESS [START] TO INITIATE SIMMER'	Indicates that the operator should press the 'START' button to begin the simmer cycle
'CHECKING FOR ARGON GAS'	No action is required. The generator is checking for connection to the gas supply
'CHECKING INLET & OUTLET VALVES'	No action required. The Generator is carrying out a self test
'CHECKING FOR GAS LEAKS'	No action required. The Generator is self-testing for chamber seal.
'WAIT SIMMERING AND PURGING'	No action required. The generator is in the "simmer" stage.
'PRESS [START] TO INITIATE BURN'	Indicates that the operator should press the START button to begin the burn cycle. Be sure you are ready to do so.
'PRESS [START] TO INITIATE THE CLEAN CYCLE'	Indicates that you must press the START button for the machine to carry out a "cleaning" function (pre-burn if selected)
'BURN VERIFIED'	No action required. Then generator is indicating that that a successful burn has been carried out.
'WAIT** GENERATING GAS'**	No action required. The generator is in the process of generating gas.
'WAIT** CLEAN CYCLE IN PROGRESS'**	Indicates that the cleaning function is in progress
'GAS READY TO USE WITHIN————'	Indication of time limit (minutes: seconds) within which you must use the Technegas
'DISCONNECT THE MAINS PLEASE'	Indicates to the operator that they must disconnect the mains supply and the Argon gas
'[START] RELEASES THE GAS VALVE'	Indicates to the operator to press the START button to unlock the patient delivery valve.
'PRESS DRAWER INTERLOCK KNOB'	If the close button is pressed without first pressing the interlock knob this message will be displayed along with an audible alarm.
'DRAWER MIDWAY OPEN OR CLOSE'	Indicates the position of the drawer. Press Open or Close to continue.
'*NO CRUCIBLE*** OR BAD CONTACTS'**	Indicates that the generator has no crucible installed or bad (old or worn) contacts. If the crucible is present, rotate the crucible back and forth a few times and try again. Next, try a new crucible followed by replacing the fixed contacts. If still in error call for service.

'– BURNS CONTACTS –MORE'	This message indicates the total number of burns carried out and the remaining number of burns for the contacts.
'CHANGE CONTACT WITHIN—BURNS' **Alternating with** **'PRESS [START] TO CONTINUE'**	Indicates to the operator that the contacts are approaching the end of their life. Pressing START at this stage will return the display to the normal screen message.
'SWITCH OFF AND CHANGE CONTACTS'	Indicates that the Contacts have reached the end of their life and must be changed. The generator should now be switched off and the crucible contacts changed. Care should be taken when changing the contacts as they may still be hot. VML recommends allowing the contacts to cool before changing.
'OPEN DRAWER AND CHANGE CONTACTS'	The above message occurs when 50 burns on the current crucible contacts have been completed. At this stage START should be pressed and the drawer opened.
'WAIT TEST CANCELLED'	This message is displayed if the CANCEL button is pressed during the simmer stage. It is not an error message and requires no action.
'CONTACTS CHANGED??' **Scrolling with** **OPEN=NO CLOSE=YES**	This message is displayed when the power is switched back on after changing the contacts. It confirms that the operator has changed the contacts and resets the Conact life counter. Pressing the appropriate button (OPEN or CLOSE) will allow normal operation.
'THE CONTACT LIFE IS NOW 50 BURNS'	Indicates the remaining lifetime of the newly installed Contacts
'SORRY THE GAS IS TOO OLD TO USE'	This message is displayed after 10 minutes has elapsed from Technegas generation. The generator will switch itself off.
'PRESS CANCEL TO EXIT OR TURN THE MAINS ON'	Indicates that you should re-initiate the machine once you have completed delivery of Technegas.
'LOW YIELD! CHECK CONTACTS'	This message indicates that the Technegas generator detected a possible LOW YIELD and requests the user check that the contacts are tight and in good condition.

MAJOR ERROR MESSAGES

'THE DRAWER FAILED TO OPEN IN THE TIME ALLOWED'	Indicates that the time allowed for the drawer to open automatically has been exceeded.
'THE DRAWER FAILED TO CLOSE IN THE TIME ALLOWED'	Indicates that the time allowed for the drawer to close automatically has been exceeded.
'CHAMBER FAILED LEAK TEST'	This indicates that the generator has found leak in the chamber and the most probable cause is that something may have jammed in the drawer front panel. Check this then retry. If still in error, call for service.
'BAD OUTLET VALVE'	This message is displayed when a fault has been detected in the gas outlet valve. Try switching off, then on again. If still in error, call for service.
'SIMMER CONTROL OUT OF RANGE'	This means that an adjustment to the Simmer Control is necessary. Try switching off, then on again. If still in error, call for service.
'ERROR IN READING PRESSURE'	This message is displayed when there is a fault in the pressure detecting section. Try switching off, then on again. If still in error, call for service.
'CRUCIBLE FAILED TO REACH FULL TEMP'	This message means that during the burn, the temperature was incorrect and a low yield of Technegas could have resulted. If low yields continue after checking/ replacing contacts call for service or further advice.
'CRUCIBLE EXCEEDED ALLOWABLE TEMP'	This message means that during the burn, the temperature was incorrect and a low yield of Technegas could have resulted.
'TRIAC FAILURE'	Indicates that the TRIAC controlling the burn temperature may have failed. Call for service advice.
'TURN OFF AND TRY AGAIN'	Indicates that the machine has had a failure and requires the power to be switched off and then back on again to reset the machine.
'SWTCH OFF AND CALL MAINTENANCE'	The generator has detected an error requiring service intervention. Call service for advice.
'PRESS CANCEL TO RESTART'	Indicates that the operator needs to press the CANCEL button. To operate, press the CANCEL button twice in two seconds to cancel an operation and restart the generator.
'CHAMBER OPEN OR NO ARGON GAS'	Indicates that no pressure was detected in the generator chamber. Normally this means that the Argon gas is either not connected or not turned on. Other possible causes could be low pressure in the Argon cylinder or something jammed in the drawer front panel.
'GAS FLOW IS TOO LOW'	Indicates that the operator should check the settings of their Argon gas supply gauges, to ensure correct flow rate. The machine is not receiving enough Argon Gas. Replace gas bottle if necessary.
'GAS FLOW IS TOO HIGH'	Indicates that the operator should check their Argon gas supply gauges and hose to the machine, to ensure correct flow rate. The machine is receiving too much Argon Gas.
'CASE TEMPERATURE TOO HIGH WAIT'	The Technegas senses that its ambient temperature is too high. No more than two burns per hour is specified."CLOCK SETTING

'ROUTINES'	Indicates that the Clock Setting Routine has begun.
'THE CLOCK HAS NOT YET BEEN SET'	The generator detects that the clock has not been set and requests the operator to follow the clock setting routine.
'CLOCK SETTING HOUR–'	Indicates that the operator may set the Hour of the clock.
'CLOCK SETTING MINUTE–'	Indicates that the operator may set the Minute of the clock.
'CLOCK SETTING YEAR –'	Indicates that the operator may set the Year of the clock.
'CLOCK SETTING MONTH – '	Indicates that the operator may set the Month of the clock.
'CLOCK SETTING DAY –'	Indicates that the operator may set the Day of the clock.

TECHNEGAS LABEL DESCRIPTIONS

1)

ATTENTION, SEE INSTRUCTIONS FOR USE

International Symbol for See Instructions for Use.

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2)

CAUTION THIS UNIT MUST BE USED IN ACCORDANCE WITH THE USER MANUAL

This label is located on the front of the Generator Trolley and requests the user to consult their User Manual when using the Generator.

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3)

OFF (POWER DISCONNECTION FROM THE MAINS)

International Symbol for power OFF.

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4)

ON (POWER CONNECTION TO THE MAINS)

International Symbol for power ON

5)

SEALED LEAD ACID RECHARGEABLE BATTERY
RATING 12V, 1.2AH

This label is located on the chassis adjacent to the battery and on batteries supplied by Cyclomedica and defines the Generator battery rating.

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6)

DEPRESS KNOB TO A POSITIVE STOP

This label is located on the Generator cover and requests the operator to push the Patient Knob fully down to release the gas.

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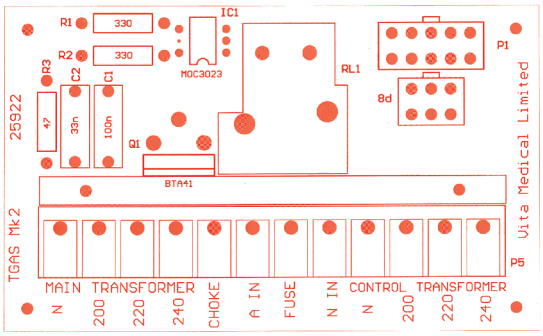
7)

PCB FUSE LABEL

This label shows a warning for the removal of the Printed Circuit Board from the unit and also defines the rating of the Printed Circuit Board Fuse in the Battery Charger line.

8)

TRANSFORMER TAPPING LABEL



This label defines the voltages for the tappings of the Generator electrical transformers.

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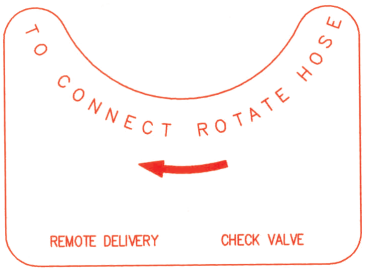
9)

ROTATE HOSE → TO CONNECT



This label is located on the front of the Generator Cover surrounding the Delivery Nozzle. It shows the direction of turn when connecting the Patient Administration Set to the Generator.

10)

USE ARGON GAS ONLY 'A'

This label is located on the Low Pressure Argon Gas Regulator. It specifies that only ARGON gas be used with the Generator.

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11)

HOT SURFACE

This symbol shown indicates the presence of a hot surface. Caution: Do not touch the hot surface as it may result in a burn injury.

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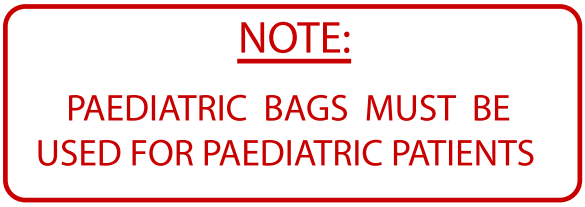
12)

PAEDIATRIC WARNING LABEL



This label indicates the use of a paediatric size resuscitator bag with the Easy Breather when used on paediatric patients.

USER MAINTENANCE
The following are the only user designated tasks for machine maintenance. Extended cleaning should be carried out at the user's discretion. Replacement of the Contact Assemblies should be carried out when prompted by the Technegas Generator.

A general Service of the Technegas Generator should be carried out by an authorised Service Person after every 150 burns or every SIX months. This includes a general cleaning and lubrication of the internal components of the Technegas Generator and importantly, calibration. Please contact your Local Distributor or Cyclomedica Australia Pty Ltd to request a service for your Technegas Generator.

Cleaning the Generator
Clean the outside of the Technegas Generator with a soft cotton cloth. For stubborn stains use a soft cotton cloth slightly moistened with water. There are no user cleanable parts inside the machine.
Do Not use Detergents or solvents such as alcohol, benzene or thinners as they will damage the finish of the unit.

Changing the Contact Assemblies
The Technegas Generator automatically counts down the remaining burns for each new set of contacts installed. The contacts must be changed every 50 Burns to ensure the untroubled operation of the Technegas Generator.
When prompted to change the contacts, open the drawer, then switch off the power at the mains switch. Loosen the Contact Clamping Screws (on the top of each pedestal) holding the contact assemblies in position. Remove the worn contact assemblies. Fit the new contact assemblies ensuring that the contact areas are clean and that when in position the rear face of both contact assemblies is in contact with the register face of the pedestals. Tighten the Contact Clamping Screws to clamp the contacts tightly. Do not over-tighten the screws as this may result in stripped threads, necessitating major repairs.
Switch the Technegas Generator back on and the message 'Contacts Changed?' appears Press the Close Key to answer YES.

Change the contact assemblies as prompted every 50 burns
Always use disposable gloves as contamination may be present
(refer Safety in Use Section)

Display Language Selection
The TechnegasPlus Generator is programmed with a number of languages with English being the default. On installation, the language for your region (if available) will be set by the Service Person. For safety, access to language setting is not available to the User. Where problems occur, please contact your local Service representative.

TECHNEGASPLUS TECHNEGAS GENERATOR SERVICE
Preventive Maintenance Service - Generator
To ensure long term operation and prevention of faults, it is recommended that the Technegas Generator undergo a Preventive Maintenance service that includes calibration each 6 months. Contact your local distributor for service.

General Service of Fault Conditions
Where a fault is perceived in the operation of the Technegas Generator, switch off the machine and call your local distributor for service. Do not operate the Technegas Generator if it is faulty.

Preventive Maintenance and Service – Easy Breather
The Easy Breather part does not contain any user maintainable components. In the case of failure or breakdown, contact your local distributor of Cyclomedica products for Service advice.

Cleaning the Easy Breather Attachment
• The external surfaces of the Easy Breather components may be wiped with a moist cloth and mild detergent or a sterilising medical wipe.
• Follow your departmental guidelines for sterilisation of the Resuscitator Bag if required.
• Cyclomedica Australia Pty Ltd recommends that you refer to the instructions for Cleaning and Sterilisation contained in the Hudson RCI Resuscitator Bag Instruction Manual.

Cleaning the Crucible Oven
• The Crucible Oven should be cleaned regularly to prevent a build up of any unwanted materials. Any materials removed from the Crucible Oven or cleaning materials may become contaminated with radiation and should be handled and disposed of accordingly.

• Always follow your Department's Radiation Safety Guidelines when handling the Crucible Oven during cleaning. If necessary, consult your Radiation Safety Officer.

Transportation
• The Technegas Plus Generator, once installed is normally a permanent fixture and requires Service Intervention to uninstall and transport to preserve its integrity of operation.
• Cyclomedica Australia Pty Ltd recommends that you contact Cyclomedica Service for instructions and/or assistance.

Storage
• The Technegas Plus Generator once installed is normally a permanent fixture and requires Service Intervention to be uninstalled and to preserve the integrity of operation.
• Cyclomedica Australia Pty Ltd recommends that you contact Cyclomedica Service for instructions and/or assistance.

Mk2 TECHNEGAS GENERATOR SPECIFICATIONS

Protection Against Electric Shock
The Degree of protection against electric shock is as per
CLASS 1 TYPE B EQUIPMENT.

- denotes Type B Applied Part

Technegas Generator Environmental
Ambient Temperature +10 - +40°C
Ambient Air Pressure 70-106 kPa (700-1060mBar)
Ambient Humidity 0-95% non condensing
Duty Cycle Two procedures per hour.

Consumables
Argon Gas
Argon Gas must be High Purity or Laboratory Grade ≥99.99% pure.

Patient Administration Set
A Patient Administration Set (PAS) designed specifically for the Technegas unit. It is manufactured from a Non-toxic plastic material, with an air filter. The PAS is for single use only.

Purge Filter Life
The Mk2 Technegas Generator is fitted with a long-life Purge Filter. The expected lifetime is a minimum of 3000 operational cycles. The Purge Filter is assessed and replaced periodically as required during the Service of the machine. The Purge Filter is not accessible by the User and must be replaced only by an approved Service provider.

End of Life Disposal of the TechnegasPlus Technegas Generator
Where your TechnegasPlus Technegas Generator has reached the end of its useful life, please refer to any local regulations for medical device product disposal.

Please ensure that an appropriate decay period has elapsed before disposal. Cyclomedica suggests a minimum of 10 half-lives of Technetium 99m before disposal.

Where further disposal or handling advice is required, please contact your local Technegas agent or the manufacturer.

Warning - The TechnegasPlus Technegas Generator contains lead (Pb) used as radiation shielding and special handling precautions should be taken.

Guidance and manufacturer's declaration – electromagnetic emissions		
The TechnegasPlus Technegas Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the TechnegasPlus Technegas Generator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The TechnegasPlus Technegas Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic TechnegasPlus Technegas Generator.
RF Emissions CISPR 11	Class A	The TechnegasPlus Technegas Generator is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in domestic and those directly connected to the public low voltage power supply network that supplies buildings used from domestic purpose environments, due to conducted disturbances.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The TechnegasPlus Technegas Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the TechnegasPlus Technegas Generator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	Complied 6 kV contact Complied 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Complied 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Complied 1 kV differential mode Complied 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% Ur (>95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Complied Complied Complied Complied	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TechnegasPlus Technegas Generator requires continued operation during power mains interruptions, it is recommended that the TechnegasPlus Technegas Generator be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	Complied < 3 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *Ur* is the a.c. mains voltage prior to the application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
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Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Complied 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Complied 1 kV differential mode Complied 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% Ur (>95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Complied Complied Complied Complied	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TechnegasPlus Technegas Generator requires continued operation during power mains interruptions, it is recommended that the TechnegasPlus Technegas Generator be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	Complied < 3 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *Ur* is the a.c. mains voltage prior to the application of the test level			

Recommended separation distances between portable and mobile RF communications equipment and the TechnegasPlus Technegas Generator			
The TechnegasPlus Technegas Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TechnegasPlus Technegas Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TechnegasPlus Technegas Generator as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = [\frac{3.5}{3}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{3}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{3}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.68	3.68	7.37
100	11.66	11.66	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

From IEC 60601-1-2 Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING -

GENERAL

Supply Voltage	200 V ~ac +/- 5% 220 V ~ac +/- 5% 230/240 V ~ac +/- 5% adjustable as above by moving a Transformer Tapping
Supply Frequency	50-60 Hz
Mains Current -	Steady State < 0.2 Ampere RMS
Mains Current -	Maximum (15 sec.) 20 Ampere RMS
Fuse	(Battery Charging)F1: Sub-Miniature Fuse Type: F (Quick Acting) Rating: 1 Amp 125V..
Shipping Weight	130 Kg
Shipping Size	1100 x 630 x 1190 (L x W x H)
Floor Area	920x600

TechnegasPlus Technegas Generator

CE 0120

RESUSCITATOR BAG SPECIFICATIONS

Storage Temperature:	-40ºC to 60ºC
Operating Temperature:	-18ºC to 50ºC
Bag Volume/Stroke Volume:	1.6 litres

The specifications quoted above are for a Hudson RCI Lifesaver Adult Reusable Resuscitator Bag.
For further information on the specifications of the Resuscitator Bag refer to the Resuscitator Bag Manual or manufacturer.

Resuscitator Bag

Component	Material	Finish
Valves	Silicon	None
Bag	Polyvinylchloride	None
O Ring	Epichlorohydrin	None
Valve Housings	Polysulphone	None

Non-Return Valve Assembly

Component	Material	Finish
Valve Body	ABS	None
Connection Spigots	ABS	None
Diaphragm	Silicon	None
Diaphragm Plate	ABS	None

PAS Check Valve

Component	Material	Finish
Valve Body	Delron	None
Valve Diaphragm	Rubber	None
Assembly Screws	Stainless Steel	None

Connector Hoses

Component	Material	Finish
Connector to Check Valve	Silicon	None

Radiation Dosimetry
The radiation absorbed dose to the lungs is somewhat higher for Technegas than for perfusion agents such as microspheres, because Technegas does not clear from the lungs within the measurable life-time of Tc-99m. However, whole body doses are comparable for a given amount of activity administered to a patient.

Absorbed dose (adult)/ 37MBq Administered.

Agent	Lung	Wholebody
Technegas	4.5mGy	0.17mGy
Microspheres (mAA) Reference (R5)	2.9mGy	0.16mGy

The Patient

Retention of inhaled Technegas in the lung is dependent on the following parameters:

- Depth of breathing
- Length of breath holding possible
- Basic condition of the patient and lungs
- Number of breaths
- The initial amount of Technetium added to the crucible
- The time after generation that the patient breathes in the Technegas

It is important to monitor the activity of the Technegas in the patient as the gas is administered by watching the count rate of a posterior view on the gamma camera console. Limit the dose to that indicated in the clinical notes (26-40MBq). This is generally a maximum of approximately 2500 counts per second (cps).

Note: If thyroid is present in images or absorption of Technegas into the blood stream is noted operators should check that they have used Argon gas of 99.99% purity. Operators should also ensure that they have used the correct eluate and have not over-filled the crucible. If such indications are present after checking these points then the operator should call their local service providor.

EASY BREATHER PRINCIPLE OF DEVICE FUNCTION

The Easy Breather Accessory has been developed to enable delivery of Technegas or Pertechnegas to any patient for whom a ventilation imaging procedure has been prescribed. Its operation is entirely pneumatic.

The Easy Breather Accessory operates in conjunction with the Technegas Generator being intended as an accessory for that device. The function of the Easy Breather Accessory is to push the Technegas from the Technegas Generator chamber to a patient via the Patient Administration Set. This is achieved by the use of the Easy Breather Accessory major component, a commercially available Resuscitator Bag. Simply, when the Resuscitator Bag is squeezed by the operator it pushes air from the bag into the Technegas Generator Chamber and then out of the Patient Delivery Valve to the patient via the standard Technegas Patient Administration Set.
A detailed Easy Breather Accessory function can be described as follows.

Patient Inhalation Cycle
When the Easy Breather Accessory Resuscitator Bag is squeezed the following actions occur (This description assumes that the Patient Delivery Valve is opened for delivery).

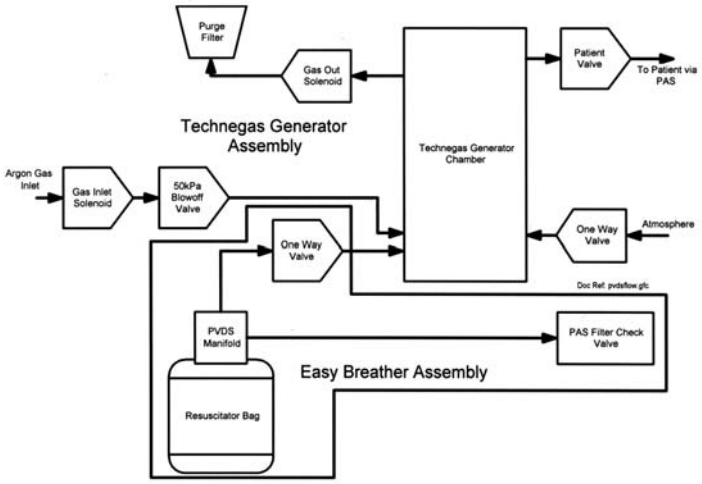
The Resuscitator Bag "Duckbill" valve opens and air is forced into the Technegas Generator Chamber via a Non Return Valve Assembly. Another Non-Return Valve Assembly from the chamber to free air shuts directing air from the Easy Breather Accessory to the chamber. When the Patient Delivery Valve is opened it provides the path for the Technegas to travel to the Patient through a standard Technegas Patient Administration Set (PAS).
At the same time, the pressure generated by squeezing the bag activates the PAS Check Valve Assembly thus blocking off the PAS exhalation path and ensuring that the Technegas to be delivered is directed only to the patient.

Patient Exhalation Cycle
For Patient Exhalation the Easy Breather Accessory Resuscitator Bag is released. The Resuscitator Bag re-inflates itself via its own inflation valve assembly located at the bottom of the bag. The pressure that operates the PAS Check Valve Assembly is also released, this allows the Check Valve to open and the patient to exhale through the PAS Filter Assembly. The Non-Return Valve Assemblies return to their normal position waiting for the next pressure cycle.

This process is repeated for each breath required to be delivered to the patient and is continued until the desired count rate for a study is achieved.

For further information, the principles of operation for the Resuscitator Bag itself are described in the Operating Manual for the Resuscitator Bag supplied by Hudson RCI.

Easy Breather Accessory Assembly Flowchart



CODE	DESCRIPTION
17838	Box of 50 Patient Administration Sets (REST OF THE WORLD)
17839	Box of 50 Patient Administration Sets (EUROPE)
10035	Patient Nose Clamp (1 only)
10036	Pair of Forceps
10029	Ash Tray
10040	Argon Gas Regulator Assembly Complete (Includes Supply Hose)
17510	Disposable Face Mask

Refer to the Service Manual for details of Service parts.

REFERENCES

References
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A full discussion of the technology and bibliography may be found at http://www.Cyclomedica.com.au

NOTES AND UPDATES